

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEVRO CORP.,)
Plaintiff,)
v.) C.A. No. _____
BOSTON SCIENTIFIC CORP. and) **DEMAND FOR JURY TRIAL**
BOSTON SCIENTIFIC)
NEUROMODULATION CORP.,)
Defendants.)

COMPLAINT

Plaintiff Nevro Corp. (“Nevro”), by and through its undersigned counsel, seeks a declaration and judgment that Defendants Boston Scientific Corporation and Boston Scientific Neuromodulation Corporation (collectively, “BSC”) deliberately and willfully infringe U.S. Patent Nos. 10,556,112 (“the ’112 patent”), 10,576,286 (“the ’286 patent”), 8,892,209 (“the ’209 patent”), 8,792,988 (“the ’988 patent”), and 9,333,357 (“the ’357 patent) (collectively, the “Asserted Patents”), which are each owned and assigned to Nevro.

NATURE OF THE ACTION

1. Chronic pain is a significant health problem that affects more Americans than diabetes, heart disease, and cancer combined. Nevro’s pioneering spinal cord stimulation technology dramatically improves the quality of life of individuals suffering from chronic pain. Nevro brings this action to stop BSC’s deliberate infringement of patents that protect Nevro’s technology.

2. Spinal cord stimulation (“SCS”) therapy attempts to relieve pain by delivering short electrical pulses to the spinal cord through small electrodes that are implanted near the spinal cord. While SCS technology has been on the market for decades, Nevro’s patented SCS

technology is significantly more effective than the traditional systems supplied by the rest of the SCS industry.

3. Traditional SCS therapy delivers electrical pulse waveforms, with frequencies on the order of 40 to 60 Hertz (Hz), to generate a sensation known as paresthesia. Paresthesia is commonly experienced as a tingling, numbness, or pins-and-needles sensation. The paresthesia is used to mask, or cover, the patient's area of pain. In theory, the patient feels the paresthesia and feels less pain.

4. For many years, it was conventional wisdom in the SCS industry that creating paresthesia was essential for SCS therapy. For example, in a BSC sponsored study, one of its own co-author scientists asserted that “[p]atient-perceived concordant paresthesia overlapping the area of pain is *essential* for success of this therapy.”¹

5. Nevro changed the SCS industry by introducing groundbreaking technology that defied conventional wisdom. Nevro recognized that traditional, paresthesia-based SCS therapy has significant failings that reduce its efficacy and limit its applicability. It is not effective in a large portion of the population, and even when it works, the pain relief is limited. Paresthesia also narrows the applicability of SCS therapy because patients often experience uncomfortable stimulations or even jolting sensations during movement, which can impair sleep or preclude driving a car while receiving therapy.

6. Nevro was founded to provide a solution to chronic pain without the drawbacks of traditional paresthesia-based SCS therapy. After years of research and development

¹ Oakley et al., “A New Spinal Cord Stimulation System Effectively Relieves Chronic, Intractable Pain: A Multicenter Prospective Clinical Study,” Neuromodulation, Vol. 10 No. 3 (2007) at 264.

work, Nevro brought to market an SCS therapy that differs dramatically from traditional SCS therapy. Nevro's SCS therapy uses unique programming of an implanted SCS system to provide pain relief without generating paresthesia. Nevro developed, tested, and patented a variety of technologies to provide paresthesia-free pain relief.

7. With its long history of providing paresthesia-based SCS therapy, Defendant BSC and the rest of the SCS industry were highly skeptical that Nevro's paresthesia-free SCS therapy would provide clinically effective pain relief. But to the industry's surprise, Nevro's paresthesia-free SCS therapy has been scientifically proven to provide significantly superior pain relief to a significantly larger population of patients. And it does so without the drawbacks of paresthesia-based SCS therapy.

8. Because Nevro's approach was fundamentally different from others in the market, the FDA put Nevro to a rigorous test. To obtain FDA approval, Nevro was required to prove that its therapy is paresthesia-free and that its therapy was clinically effective even though it is paresthesia-free. To obtain FDA approval, Nevro tested its 10,000 Hz paresthesia-free SCS therapy – its commercially marketed HF10® therapy – against Defendant BSC's paresthesia-based SCS system, in an FDA-monitored randomized, controlled, trial. The trial showed that Nevro's paresthesia-free SCS therapy is not only clinically effective without paresthesia, but also is nearly *twice as effective* as BSC's paresthesia-based SCS therapy. As a result, when the FDA granted approval for Nevro's 10,000 Hz SCS therapy on May 8, 2015, it awarded Nevro's SCS therapy a rare “superiority” label—allowing Nevro to claim its SCS therapy is clinically superior to BSC's paresthesia-based SCS therapy.

9. Nevro's SCS systems provide more effective pain relief to a greater percentage of patients. Traditional, paresthesia-based SCS therapy has limited use. For example,

patients with predominant back pain are seldom seen as good candidates for traditional SCS therapy because it is anatomically difficult to cover the back with paresthesia. In contrast, Nevro's SCS systems provide significant and sustained pain relief for both back and leg pain. Importantly, Nevro's SCS systems and therapy also provide patients with greater freedom of movement and activity. Paresthesia-based SCS therapies can cause unexpected jolts or shocks when a patient bends, twists, or changes posture, and must be turned off while driving or sleeping. Nevro's therapy does not have any such restrictions. Nevro's unique—and demonstrably superior—SCS technology has been the key to Nevro breaking into and obtaining significant market share in the U.S. SCS market.

10. What started out as skepticism has turned into copying. Witnessing Nevro's superior results and rapid success, Defendant BSC has desperately tried to mimic every step of Nevro's innovations in SCS therapy. In 2012, BSC executives exchanged emails noting that their employees perceived BSC's "clinical research [as] short term focused . . . or essentially me-too approaches (DBS), but not innovative in nature."² The BSC executives concluded "*[t]hat is why we will need to copy or acquire approaches developed by others (Nevro, Spinal Modulation, Neurosigma, etc.). It is those places where innovation takes place . . .*"³

11. Shortly thereafter, BSC aggressively acted on its executives' urgent call to copy Nevro's innovative technology. In March 2014, BSC initiated the ACCELERATE clinical trial in the U.S. copying Nevro's HF10® therapy and seeking FDA approval of paresthesia-free

² *Nevro Corp. v. Boston Scientific Corp.*, C.A. No. 3:16-cv-06830, D.I. 202-8 (N.D. Cal. Nov. 16, 2017) ("California Action").

³ *Id.*

therapy.⁴ In December 2014, BSC initiated the WHISPER clinical trial trying to mimic Nevro's paresthesia-free therapy at lower frequency ranges.⁵ BSC employees also stated that “[w]e should . . . get as much information as possible on what Nevro's use model and programming is so that we can make something that addresses the need and not something that gets close to it only.”

12. BSC has continually and repeatedly copied Nevro's products and patented technology. Upon information and belief, BSC undertook a repeated and concentrated effort to copy Nevro's therapies as BSC tried developing competing devices and therapy options. Upon information and belief, prior to Nevro's success, BSC did not even consider developing paresthesia-free therapy. Upon information and belief, when BSC embarked on developing paresthesia-free SCS therapy, BSC copied Nevro's technology.⁶ For instance, upon information and belief, BSC began investigating a paresthesia-free therapy option at 1,200 Hz as a direct response to Nevro's paresthesia-free therapy so that BSC could try to compete with Nevro. Upon information and belief, BSC engineers reviewed Nevro's patents, products, website, conference presentations, and other materials to aid in BSC's product development.⁷ Upon information and belief, BSC has worked with doctors and experts to study Nevro's products so that BSC can copy them. BSC even tried to invalidate one of Nevro's patents (U.S. Patent No. 8,359,102) to clear the way for its copying, but the U.S. Patent Office definitively rejected that attempt.

⁴ California Action, D.I. 202-6 at 1; *see also* D.I. 158 at ¶ 8; <https://clinicaltrials.gov/ct2/show/NCT02093793>.

⁵ <https://clinicaltrials.gov/ct2/show/NCT02314000>

⁶ *See* California Action, D.I. 202-8.

⁷ *See* California Action, D.I. 202-6.

13. Years of litigation between BSC and Nevro has revealed a continual pattern of BSC watching Nevro's innovations and copying them to maintain and advance BSC's competitiveness in the SCS market.

14. To protect its patented technology, on November 28, 2016, Nevro filed a patent infringement lawsuit against BSC in the Northern District of California alleging infringement of certain claims of six Nevro patents directed to high-frequency, paresthesia-free therapy. In response to that lawsuit, BSC pivoted and *de-designed* its Spectra WaveWriter System so that it no longer was capable of delivering SCS therapy over 1,200 Hz. BSC also decelerated its ACCELERATE trial, and canceled its plans to release products that could perform high-frequency, paresthesia-free therapy. In December 2020, on the condition that BSC is scrapping its current plans to launch a high frequency, paresthesia-free product that mimicked Nevro's HF10® therapy, Nevro reached an agreement with BSC to dismiss the California litigation.

15. Notwithstanding Nevro's success in the California litigation, BSC has continued to seek ways in which it could configure and market its products to copy Nevro's innovations. BSC knew that it needed to copy Nevro's paresthesia-free therapy or it will lose its competitiveness in the SCS market. In this regard BSC initiated clinical trials, called WHISPER, PROCO, and HALO, providing stimulation at lower frequencies, for example 1,200 Hz, and has started to program its devices to provide paresthesia-free therapy at those frequencies, again copying Nevro.⁸

16. Just days after the dismissal of the California lawsuit, BSC announced that the FDA had approved a new set of products, called "WaveWriter Alpha," designed to copy

⁸ North American Neuromodulation Society Investor Update (January 12, 2018) at 8.

Nevro's paresthesia-free technology at lower frequencies.⁹ These products include the WaveWriter Alpha, the WaveWriter Alpha 16, the WaveWriter Alpha Prime, and the WaveWriter Alpha Prime 16. BSC has announced that the WaveWriter Alpha products can provide paresthesia-free therapy using BSC's FAST and Contour therapies.¹⁰ On information and belief, the WaveWriter Alpha products also support BSC's Whisper 3D and HR3D sub-perception therapies. In January 2021, BSC announced "a limited market release" of its WaveWriter Alpha SCS system, which BSC touted as being "designed to deliver profound paresthesia-free pain relief in minutes."¹¹ As BSC was well aware, all of those newly launched products also infringe Nevro's patents.

17. BSC launched the Alpha products in January 2021 despite being acutely aware that Nevro's paresthesia-free technology is patent-protected. For instance, in the recently dismissed California litigation, Nevro had asserted patents that included claims covering its paresthesia-free technology regardless of frequency; namely U.S. Patent Nos. 8,792,988 and 9,333,357. Nevertheless, BSC recognized that its competitiveness in the SCS market will significantly diminish unless it finds another way to copy Nevro's paresthesia-free therapy. BSC has therefore aggressively pursued commercialization of lower frequency, paresthesia-free SCS products – through its new Alpha product line – in blatant violation of Nevro's intellectual property

⁹ <https://www.prnewswire.com/news-releases/boston-scientific-launches-wavewriter-alpha-spinal-cord-stimulator-systems-in-us-301208156.html>

¹⁰ <https://www.bostonscientific.com/en-US/medical-specialties/pain-medicine/wavewriter-alpha-scs.html>

¹¹ <https://news.bostonscientific.com/2021-01-14-Boston-Scientific-Launches-WaveWriter-Alpha-TM-Spinal-Cord-Stimulator-Systems-In-U-S>

rights, and despite knowing that Nevro also has patent claims directed to lower frequency, paresthesia-free therapy.

18. Nevro will be irreparably harmed if Boston Scientific is permitted to continue to manufacture, use, offer to sell, and sell infringing devices. Nevro will be forced to compete against the very technology that it spent years researching, developing and bringing to market. Nevro does not license its technology to anyone else. This differentiating technology, developed in the face of the skepticism of BSC and the SCS industry, has been the key to Nevro's ability to break into a market that has been dominated for decades by three of the largest medical device companies in the world (Medtronic, St. Jude, and BSC). Nevro's marketing strategy has been built around educating physicians, health care providers and consumers about the enhanced performance of its paresthesia-free SCS therapy, in comparison with traditional paresthesia-based SCS therapy. If BSC is permitted to continue to sell infringing paresthesia-free device, Nevro will lose its key distinguishing feature, and other companies will feel free to launch their own competing, infringing devices.

THE PARTIES

19. Plaintiff Nevro is a Delaware corporation with its principal place of business at 1800 Bridge Parkway, Redwood City, CA 94065.

20. Defendant Boston Scientific Corporation is a Delaware corporation with its principal place of business at 300 Boston Scientific Way, Marlborough, MA 01752, and defendant Boston Scientific Neuromodulation Corporation is a Delaware corporation with its principal place of business at 25155 Rye Canyon Loop, Valencia, California 91355. On information and belief, Boston Scientific Neuromodulation Corporation operates as a wholly-owned subsidiary of Boston Scientific Corporation, acts at Boston Scientific Corporation's direction and control and for Boston Scientific Corporation's direct benefit, and is controlled by Boston Scientific Corporation.

JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

22. This Court has personal jurisdiction over BSC because it is a Delaware corporation. Upon information and belief, BSC is a resident of this judicial district, has systematic and continuous contacts in this judicial district, regularly transacts business within this district, and regularly avails itself of the benefits of this district. Upon information and belief, BSC also sells the accused infringing products and derives substantial revenues from sales in this district.

23. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b) in that BSC is subject to personal jurisdiction in this District.

FIRST CAUSE OF ACTION
(Infringement of U.S. Patent No. 10,556,112)

24. Nevro incorporates paragraphs 1-23 as though fully set forth herein.

25. Nevro is the owner of all rights, title, and interest in and to the '112 patent. The '112 patent issued on February 11, 2020, and is titled "Spinal Cord Modulation for Inhibiting Pain via Short Pulse Width Waveforms, and Associated Systems and Methods." A copy of the '112 patent is attached as Exhibit 1.

26. The innovations of the '112 patent significantly improve existing SCS technology. The '112 patent explains, for example, how "short pulse width characteristics of the signal, alone or in combination with other signal parameters (e.g., frequency and/or amplitude) can produce pain relief without using the generation of paresthesia to mask the patient's sensation of pain." 2:22-63. The '112 patent further explains how to "provide simplified spinal cord modulation systems and components, and simplified procedures for the practitioner and/or the patient." *Id.* Similarly, the patent explains that "an expected benefit of short pulse width

waveforms (e.g., having pulse widths within the ranges described above) is that when applied at the appropriate amplitude, to the appropriate neural population, such pulses can effectively reduce or eliminate patient pain without the signal producing, creating, or generating paresthesia. In addition to providing pain relief without paresthesia, such waveforms can produce pain relief with less power than is required for waveforms having longer pulse widths, depending upon the values selected for other signal delivery parameters.” 9:26-10:34.

27. Accordingly, the claims of the ’112 patent provide a significant advancement over the prior art. For example, the prior art neither teaches nor suggests the claimed methods and apparatus for reducing or eliminating pain. These advancements were neither well-known, routine, nor conventional. On information and belief, a person of ordinary skill in the art would have viewed the invention of the ’112 patent as a patentable advancement over the prior art.

28. The claims of the ’112 patent cover an inventive spinal cord stimulation system for reducing or eliminating pain in a patient and associated systems and methods. BSC has infringed and continues to infringe one or more claims of the ’112 patent, literally or under the doctrine of equivalents, including, without limitation, claim 1 in violation of 35 U.S.C. § 271(a) by manufacturing, using, selling and/or offering to sell in the United States certain SCS systems.

29. For example, claim 1 of the ’112 patent recites:

- a) A spinal cord stimulation system for reducing or eliminating pain in a patient, the system comprising:
- b) an implantable signal generator that, in operation, generates a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal is at a frequency of from 500 Hz to 1,200 Hz, with a pulse width in a pulse width range from 10 microseconds to 50 microseconds, and a current amplitude in a current amplitude range from 0.5 mA to 7 mA; and
- c) a signal delivery device electrically coupled to the implantable signal generator to deliver the therapy signal to the dorsal column of the patient's spinal cord.

30. To the extent the preamble of claim 1 is considered a limitation, at least the BSC Precision Novi, Precision Spectra, Precision Montage, Spectra WaveWriter, WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise a spinal cord stimulation system for reducing or eliminating pain in a patient. Additional information is set forth in Exhibit 2 at claim 1(a).

31. At least the BSC Precision Novi, Precision Spectra, Precision Montage, Spectra WaveWriter, WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise a an implantable signal generator that, in operation, generates a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal is at a frequency of from 500 Hz to 1,200 Hz, with a pulse width in a pulse width range from 10 microseconds to 50 microseconds, and a current amplitude in a current amplitude range from 0.5 mA to 7 mA. Additional information is set forth in Exhibit 2 at claim 1(b).

32. At least the BSC Precision Novi, Precision Spectra, Precision Montage, Spectra WaveWriter, WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise a signal delivery device electrically coupled to the implantable signal generator to deliver the therapy signal to the dorsal column of the patient's spinal cord. Additional information is set forth in Exhibit 2 at claim 1(c).

33. On information and belief, BSC knows of or has been willfully blind to the existence of the '112 patent. To protect its patented technology, on November 28, 2016, Nevro filed a patent infringement lawsuit against BSC in the Northern District of California alleging infringement of six patents directed to paresthesia-free therapy. Nevro also asserted a claim of patent infringement against BSC in Delaware on December 9, 2019, based on another patent directed to paresthesia-free therapy (U.S. Patent No. 10,149,978), which is in the same family as

the '112 patent. In those cases, Nevro provided BSC with detailed contentions explaining how BSC's SCS products infringe claims directed to paresthesia-free therapy. Accordingly, BSC has not only known or been willfully blind to the '112 patent, but BSC has also known that its SCS products infringe the '112 patent.

34. In past legal filings, BSC also alleged that "it is standard practice in the SCS industry to monitor competitors' patent portfolios," and that "[i]t is standard practice to conduct competitive intelligence when sued and to conduct a presuit investigation prior to initiating a lawsuit." Accordingly, on information and belief, BSC must itself monitor Nevro's patent portfolio, whereby BSC obtained actual and constructive knowledge of the Asserted Patents. On information and belief, BSC investigated Nevro's patent portfolio prior to copying Nevro's paresthesia-free innovations, whereby BSC obtained actual and constructive knowledge of the '112 patent.

35. Furthermore, BSC has repeatedly referenced Nevro's website, www.nevro.com, in legal filings. On its website, Nevro identifies by patent number, issue date and title those patents, including the '112 patent, that may protect the Senza® system, either alone or in combination with its accessories, kits and procedures. Nevro's regular practice is to publish those relevant patents on its website. As a result, BSC has known or has been willfully blind to the existence of the '112 patent.

36. On information and belief, BSC has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use its SCS systems in a manner that infringes the '112 patent, literally or under the doctrine of equivalents. As is common in the SCS industry, BSC's clinical engineers and/or sales representatives are normally present in the operating room and will program the SCS device for the operation, including by

setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. BSC knows or has been willfully blind to the fact that such actions are inducing, and will induce, infringement. The foregoing actions by BSC constitute, and will constitute, induced infringement of one or more claims of the '112 patent in violation of 35 U.S.C. § 271(b).

37. On information and belief, BSC has contributed to infringement by others of one or more claims of the '112 patent by offering to sell or selling in the United States and/or importing into the United States its infringing SCS systems and/or components of its infringing SCS systems. As described above, these SCS systems and/or components are components of a patented machine, manufacture, combination or composition and constitute a material part of the inventions claimed in the '112 patent. Also as described above, BSC knows or has been willfully blind to the fact that these infringing SCS systems and/or components are especially made or especially adapted for use in an infringement of the '112 patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use. As is common in the SCS industry, BSC has offered to sell, sold, and/or imported its infringing SCS systems and components to doctors, hospitals and other health care providers. These doctors, hospitals and other health care providers then make, use, sell, or offer to sell systems that utilize these infringing SCS systems and/or components. For example, BSC has represented that “[t]he Spectra WaveWriter system supports any combination of 8 contact percutaneous, 16 contact percutaneous, and 16 contact surgical leads totaling up to 32 active contacts.”¹² On information and belief, the infringing SCS

¹² https://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/91157700-03_Rev_A_Spectra%20WaveWriter%E2%84%A2_System_Implantable_Pulse_Generator_DFU_en-US_s.pdf.

systems are capable of incorporating other manufacturers' leads.¹³ The foregoing actions by BSC constitute, and will constitute, contributory infringement of one or more claims of the '112 patent in violation of 35 U.S.C. § 271(c).

38. BSC's infringement is without the consent or other authority of Nevro. BSC is not licensed under the '112 patent.

39. BSC's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285.

40. Nevro has been damaged by BSC's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, BSC's continued acts of infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring BSC from further infringement of the '112 patent.

SECOND CAUSE OF ACTION
(Infringement of U.S. Patent No. 10,576,286)

41. Nevro incorporates paragraphs 1-40 as though fully set forth herein.

42. Nevro is the owner of all rights, title, and interest in and to the '286 patent. The '286 patent issued on March 3, 2020, and is titled "Spinal Cord Modulation for Inhibiting Pain via Short Pulse Width Waveforms, and Associated Systems and Methods." A copy of the '286 patent is attached as Exhibit 3.

43. The innovations of the '286 patent significantly improve existing SCS technology. The '286 patent explains, for example, how "the short pulse width characteristics of

¹³ https://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/90893429-09RevA_Precision_M8_Adapter_DFU_en-US_S.pdf at 3 ("The Precision™ M8 Adapter is a 1 x 8 in-line connector that is designed to connect specific Medtronic® leads to the Boston Scientific SCS implantable pulse generators, OR Cables, leads and lead extensions, as part of a spinal cord stimulation procedure.").

the signal, alone or in combination with other signal parameters (e.g., frequency and/or amplitude) can produce pain relief without using the generation of paresthesia to mask the patient's sensation of pain.” 2:23-63. The ’286 patent also explains how to “provide simplified spinal cord modulation systems and components, and simplified procedures for the practitioner and/or the patient.” *Id.* Similarly, the ’286 patent explains that “an expected benefit of short pulse width waveforms (e.g., having pulse widths within the ranges described above) is that when applied at the appropriate amplitude, to the appropriate neural population, such pulses can effectively reduce or eliminate patient pain without the signal producing, creating, or generating paresthesia. In addition to providing pain relief without paresthesia, such waveforms can produce pain relief with less power than is required for waveforms having longer pulse widths.” 9:21-10:29.

44. Accordingly, the claims of the ’286 patent provide a significant advancement over the prior art. For example, the prior art neither teaches nor suggests the claimed methods and apparatus for reducing or eliminating pain. These advancements were neither well-known, routine, nor conventional. On information and belief, a person of ordinary skill in the art would have viewed the invention of the ’286 patent as a patentable advancement over the prior art.

45. The claims of the ’286 patent cover an inventive spinal cord modulation and associated systems and methods for inhibiting pain via waveforms with short pulse widths and associated systems and methods. BSC has infringed and continues to infringe one or more claims of the ’286 patent, literally or under the doctrine of equivalents, including, without limitation, claim 1 in violation of 35 U.S.C. § 271(a) by manufacturing, using, selling and/or offering to sell in the United States certain SCS systems.

46. For example, claim 1 of the ’286 patent recites:

- a) A method for reducing or eliminating pain in a patient, without causing paresthesia in the patient, the method comprising:

- b) programming a computer-readable medium of an implanted signal generator to:
- c) generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal is at a frequency of from 500 Hz to 1.2 kHz, with a pulse width in a pulse width range from 10 microseconds to 50 microseconds, and a current amplitude in a current amplitude range from 0.5 mA to 20 mA; and
- d) transmit the therapy signal to the dorsal column of the patient's spinal cord via a signal delivery device implanted in the patient's epidural space and electrically coupled to the implanted signal generator.

47. To the extent the preamble of claim 1 is considered a limitation, at least the BSC Precision Novi, Precision Spectra, Precision Montage, Spectra WaveWriter, WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise a method for reducing or eliminating pain in a patient, without causing paresthesia in the patient. Additional information is set forth in Exhibit 4 at claim 1(a).

48. At least the BSC Precision Novi, Precision Spectra, Precision Montage, Spectra WaveWriter, WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise a programming a computer-readable medium of an implanted signal generator. Additional information is set forth in Exhibit 4 at claim 1(b).

49. At least the BSC Precision Novi, Precision Spectra, Precision Montage, Spectra WaveWriter, WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal is at a frequency of from 500 Hz to 1.2 kHz, with a pulse width in a pulse width range from 10 microseconds to 50 microseconds, and a current amplitude in a current amplitude range from 0.5 mA to 20 mA. Additional information is set forth in Exhibit 4 at claim 1(c).

50. At least the BSC Precision Novi, Precision Spectra, Precision Montage, Spectra WaveWriter, WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS

systems transmit the therapy signal to the dorsal column of the patient's spinal cord via a signal delivery device implanted in the patient's epidural space and electrically coupled to the implanted signal generator. Additional information is set forth in Exhibit 4 at claim 1(d).

51. On information and belief, BSC knows of or has been willfully blind to the existence of the '286 patent. To protect its patented technology, on November 28, 2016, Nevro filed a patent infringement lawsuit against BSC in the Northern District of California alleging infringement of six patents directed to paresthesia-free therapy. Nevro also asserted a claim of patent infringement against BSC in Delaware on December 9, 2019, based on another patent directed to paresthesia-free therapy (U.S. Patent No. 10,149,978), which is in the same family as the '286 patent. In those cases, Nevro provided BSC with detailed contentions explaining how BSC's SCS products infringe claims directed to paresthesia-free therapy. Accordingly, BSC has not only known or been willfully blind to the '286 patent, but BSC has also known that its SCS products infringe the '286 patent.

52. In past legal filings, BSC also alleged that "it is standard practice in the SCS industry to monitor competitors' patent portfolios," and that "[i]t is standard practice to conduct competitive intelligence when sued and to conduct a presuit investigation prior to initiating a lawsuit." Accordingly, on information and belief, BSC must itself monitor Nevro's patent portfolio, whereby BSC obtained actual and constructive knowledge of the Asserted Patents. On information and belief, BSC investigated Nevro's patent portfolio prior to copying Nevro's paresthesia-free innovations, whereby BSC obtained actual and constructive knowledge of the '286 patent.

53. Furthermore, BSC has repeatedly referenced Nevro's website, www.nevro.com, in legal filings. On its website, Nevro identifies by patent number, issue date

and title those patents, including the '286 patent, that may protect the Senza® system, either alone or in combination with its accessories, kits and procedures. Nevro's regular practice is to publish those relevant patents on its website. As a result, BSC has known or has been willfully blind to the existence of the '286 patent.

54. On information and belief, BSC has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use its SCS systems in a manner that infringes the '286 patent, literally or under the doctrine of equivalents. As is common in the SCS industry, BSC's clinical engineers and/or sales representatives are normally present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. BSC knows or has been willfully blind to the fact that such actions are inducing, and will induce, infringement. The foregoing actions by BSC constitute, and will constitute, induced infringement of one or more claims of the '286 patent in violation of 35 U.S.C. § 271(b).

55. On information and belief, BSC has contributed to infringement by others of one or more claims of the '286 patent by offering to sell or selling in the United States and/or importing into the United States its infringing SCS systems and/or components of its infringing SCS systems. As described above, these SCS systems and/or components are components of a patented machine, manufacture, combination or composition and constitute a material part of the inventions claimed in the '286 patent. Also as described above, BSC knows or has been willfully blind to the fact that these infringing SCS systems and/or components are especially made or especially adapted for use in an infringement of the '286 patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use. As is common in the SCS

industry, BSC has offered to sell, sold, and/or imported its infringing SCS systems and components to doctors, hospitals and other health care providers. These doctors, hospitals and other health care providers then make, use, sell, or offer to sell systems that utilize these infringing SCS systems and/or components. For example, BSC has represented that “[t]he Spectra WaveWriter system supports any combination of 8 contact percutaneous, 16 contact percutaneous, and 16 contact surgical leads totaling up to 32 active contacts.”¹⁴ On information and belief, the infringing SCS systems are capable of incorporating other manufacturers’ leads.¹⁵ The foregoing actions by BSC constitute, and will constitute, contributory infringement of one or more claims of the ’286 patent in violation of 35 U.S.C. § 271(c).

56. BSC’s infringement is without the consent or other authority of Nevro. BSC is not licensed under the ’286 patent.

57. BSC’s actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285.

58. Nevro has been damaged by BSC’s acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, BSC’s continued acts of infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring BSC from further infringement of the ’286 patent.

¹⁴ https://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/91157700-03_Rev_A_Spectra%20WaveWriter%E2%84%A2_System_Implantable_Pulse_Generator_DFU_en-US_s.pdf.

¹⁵ https://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/90893429-09RevA_Precision_M8_Adapter_DFU_en-US_S.pdf at 3 (“The Precision™ M8 Adapter is a 1 x 8 in-line connector that is designed to connect specific Medtronic® leads to the Boston Scientific SCS implantable pulse generators, OR Cables, leads and lead extensions, as part of a spinal cord stimulation procedure.”).

THIRD CAUSE OF ACTION
(Infringement of U.S. Patent No. 8,892,209)

59. Nevro incorporates paragraphs 1-58 as though fully set forth herein.
60. Nevro is the owner of all rights, title, and interest in and to the '209 patent.

The '209 patent issued on November 18, 2014, and is titled "Selective high Frequency Spinal Cord Modulation for Inhibiting Pain with Reduced Side Effects, and Associated Systems and Methods."

A copy of the '209 patent is attached as Exhibit 5.

61. The innovations of the '209 patent significantly improve existing SCS technology. The '209 patent explains, for example, how to reduce or eliminate pain "with reduced or eliminated side effects. Such side effects can include unwanted motor stimulation or blocking, and/or interference with sensory functions other than the targeted pain." 2:52-3:12. The '209 patent also describes "simplified spinal cord modulation systems and components, and simplified procedures for the practitioner and/or the patient." *Id.* Similarly, the '209 patent explains how to provide "a significant pain reduction that is largely independent of the patient's movement and position. In particular, the patient can assume a variety of positions and/or undertake a variety of movements associated with activities of daily living and/or other activities, without the need to adjust the parameters in accordance with which the therapy is applied to the patient (e.g., the signal amplitude). This result can greatly simplify the patient's life and reduce the effort required by the patient to experience pain relief while engaging in a variety of activities. This result can also provide an improved lifestyle for patients who experience pain during sleep." 15:43-19:4. In addition, the innovations of the '209 patent enable a "gradual change" in therapy level that "is unlike typical changes associated with conventional SCS therapies." *Id.* This allows "the patient to more freely change signal delivery parameters and/or posture when desired, without fear of creating an immediately painful effect." *Id.* The innovations of the '209 patent further enable

“greater patient range of motion without triggering undesirable side effects,” by providing a “relatively broad” amplitude “‘window’ between the onset of effective therapy and the onset of pain or discomfort,” in comparison to conventional therapy. *Id.*

62. Accordingly, the claims of the ’209 patent provide a significant advancement over the prior art. For example, the prior art neither teaches nor suggests the claimed methods and apparatus for reducing or eliminating pain. These advancements were neither well-known, routine, nor conventional. On information and belief, a person of ordinary skill in the art would have viewed the invention of the ’209 patent as a patentable advancement over the prior art.

63. The claims of the ’209 patent cover inventive spinal cord modulation and associated systems and methods for inhibiting pain and associated systems and methods. BSC has infringed and continues to infringe one or more claims of the ’209 patent, literally or under the doctrine of equivalents, including, without limitation, claim 1 in violation of 35 U.S.C. § 271(a) by manufacturing, using, selling and/or offering to sell in the United States certain SCS systems.

64. For example, claim 1 of the ’209 patent recites:

- a) A spinal cord modulation system for reducing or eliminating pain in a patient, the system comprising:
- b) a pulse generator configured to generate a non-paresthesia-producing therapy signal, wherein the therapy signal includes a plurality, of sequential bi-phasic pulses with pulse widths between 10 microseconds to 333 microseconds; and
- c) an implantable signal delivery device electrically coupled to the pulse generator and configured to deliver the therapy signal to the patient's spinal cord.

65. To the extent the preamble of claim 1 is considered a limitation, at least the BSC Precision Novi, Precision Spectra, Precision Montage, Spectra WaveWriter, WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise a spinal cord

modulation system for reducing or eliminating pain in a patient. Additional information is set forth in Exhibit 6 at claim 1(a).

66. At least the BSC Precision Novi, Precision Spectra, Precision Montage, Spectra WaveWriter, WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise a pulse generator configured to generate a non-paresthesia-producing therapy signal, wherein the therapy signal includes a plurality, of sequential bi-phasic pulses with pulse widths between 10 microseconds to 333 microseconds. Additional information is set forth in Exhibit 6 at claim 1(b).

67. At least the BSC Precision Novi, Precision Spectra, Precision Montage, Spectra WaveWriter, WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise an implantable signal delivery device electrically coupled to the pulse generator and configured to deliver the therapy signal to the patient's spinal cord. Additional information is set forth in Exhibit 6 at claim 1(c).

68. On information and belief, BSC knows of or has been willfully blind to the existence of the '209 patent. To protect its patented technology, on November 28, 2016, Nevro filed a patent infringement lawsuit against BSC in the Northern District of California alleging infringement of six patents directed to paresthesia-free therapy, some of which are in the same family as the '209 patent. Nevro also asserted a claim of patent infringement against BSC in Delaware on December 9, 2019, based on another patent directed to paresthesia-free therapy (U.S. Patent No. 10,149,978). In those cases, Nevro provided BSC with detailed contentions explaining how BSC's SCS products infringe claims directed to paresthesia-free therapy. Accordingly, BSC has not only known or been willfully blind to the '209 patent, but BSC has also known that its SCS products infringe the '209 patent.

69. In past legal filings, BSC also alleged that “it is standard practice in the SCS industry to monitor competitors’ patent portfolios” and that “[i]t is standard practice to conduct competitive intelligence when sued and to conduct a presuit investigation prior to initiating a lawsuit.” Accordingly, on information and belief, BSC must itself monitor Nevro’s patent portfolio, whereby BSC obtained actual and constructive knowledge of the Asserted Patents. On information and belief, BSC investigated Nevro’s patent portfolio prior to copying Nevro’s paresthesia-free innovations, whereby BSC obtained actual and constructive knowledge of the ’209 patent.

70. Furthermore, BSC has repeatedly referenced Nevro’s website, www.nevro.com, in legal filings. On its website, Nevro identifies by patent number, issue date and title those patents, including the ’209 patent, that may protect the Senza® system, either alone or in combination with its accessories, kits and procedures. Nevro’s regular practice is to publish those relevant patents on its website. As a result, BSC has known or has been willfully blind to the existence of the ’209 patent.

71. On information and belief, BSC has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use its SCS systems in a manner that infringes the ’209 patent, literally or under the doctrine of equivalents. As is common in the SCS industry, BSC’s clinical engineers and/or sales representatives are normally present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. BSC knows or has been willfully blind to the fact that such actions are inducing, and will induce, infringement. The foregoing actions by BSC constitute, and will

constitute, induced infringement of one or more claims of the '209 patent in violation of 35 U.S.C. § 271(b).

72. On information and belief, BSC has contributed to infringement by others of one or more claims of the '209 patent by offering to sell or selling in the United States and/or importing into the United States its infringing SCS systems and/or components of its infringing SCS systems. As described above, these SCS systems and/or components are components of a patented machine, manufacture, combination or composition and constitute a material part of the inventions claimed in the '209 patent. Also as described above, BSC knows or has been willfully blind to the fact that these infringing SCS systems and/or components are especially made or especially adapted for use in an infringement of the '209 patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use. As is common in the SCS industry, BSC has offered to sell, sold, and/or imported its infringing SCS systems and components to doctors, hospitals and other health care providers. These doctors, hospitals and other health care providers then make, use, sell, or offer to sell systems that utilize these infringing SCS systems and/or components. For example, BSC has represented that “[t]he Spectra WaveWriter system supports any combination of 8 contact percutaneous, 16 contact percutaneous, and 16 contact surgical leads totaling up to 32 active contacts.”¹⁶ On information and belief, the infringing SCS systems are capable of incorporating other manufacturers’ leads.¹⁷ The foregoing actions by BSC

¹⁶ https://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/91157700-03_Rev_A_Spectra%20WaveWriter%E2%84%A2_System_Implantable_Pulse_Generator_DFU_en-US_s.pdf.

¹⁷ https://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/90893429-09RevA_Precision_M8_Adapter_DFU_en-US_S.pdf at 3 (“The Precision™ M8 Adapter is a 1 x 8 in-line connector that is designed to connect specific Medtronic® leads to the Boston Scientific SCS implantable pulse generators, OR Cables, leads and lead extensions, as part of a spinal cord stimulation procedure.”).

constitute, and will constitute, contributory infringement of one or more claims of the '209 patent in violation of 35 U.S.C. § 271(c).

73. BSC's infringement is without the consent or other authority of Nevro. BSC is not licensed under the '209 patent.

74. BSC's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285.

75. Nevro has been damaged by BSC's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, BSC's continued acts of infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring BSC from further infringement of the '209 patent.

FOURTH CAUSE OF ACTION
(Infringement of U.S. Patent No. 8,792,988)

76. Nevro incorporates paragraphs 1-75 as though fully set forth herein.

77. Nevro is the owner of all rights, title, and interest in and to the '988 patent. The '988 patent issued on July 29, 2014, and is titled "Selective High Frequency Spinal Cord Modulation for Inhibiting Pain with Reduced Side Effects, and Associated Systems and Methods." A copy of the '988 patent is attached as Exhibit 7.

78. The innovations of the '988 patent significantly improve existing SCS technology. The '988 patent explains, for example, how to "reduce[] pain by 42% when compared with standard SCS therapy," without paresthesia. 7:44-45. The '988 patent further explains how to inhibit pain "with reduced or eliminated side effects. Such side effects can include unwanted motor stimulation or blocking, and/or interference with sensory functions other than the targeted pain." 2:53-62. The '988 patent further explains how to "provide simplified spinal cord modulation systems and components, and simplified procedures for the practitioner and/or the

patient.” *Id.* The simplified procedures can include eliminating the conventional “trial and error process (or parts of this process) for identifying a suitable lead location and associated signal delivery parameters during the lead implant procedure,” and also significantly simplifying “the process of selecting signal delivery parameters and administering the signals on a long-term basis.” 5:52-60. The innovations of the ’988 patent also enable patients to significantly improve their daily activities, “ranging from 30% for eating to 80%-90% for standing, walking and climbing stairs,” compared to “only about 10%-20%” improvement using conventional SCS therapy. 8:30-49. This “greatly simplif[ies] the patient’s life and reduce the effort required by the patient to experience pain relief while engaging in a variety of activities.” 16:4-9. Patients also experienced less muscle spasms, cramps, and muscle pain, compared to standard SCS therapy. 9:21-29. The innovations of the ’988 patent further provide “amplitude ‘window’ between the onset of effective therapy and the onset of pain or discomfort is relatively broad, and in particular, broader than it is for standard SCS treatment,” and also “allow the practitioner to provide modulation over a broader range of amplitudes” compared to conventional technology. 16:50-54, 17:24-27. Furthermore, using the ’988 patent’s innovations, “the practitioner need not implant the lead with the same level of precision as is typically required for standard SCS lead placement,” and may significantly reduce the “need for conducting a mapping procedure at the time the lead is implanted.” 17:50-53. The ’988 patent provides such benefits, while at the same time allowing easier design and manufacture, due to its superior technology. 23:45-49.

79. Accordingly, the claims of the ’988 patent provide a significant advancement over the prior art. For example, the prior art neither teaches nor suggests the claimed methods and apparatus for reducing or eliminating pain. These advancements were neither well-

known, routine, nor conventional. On information and belief, a person of ordinary skill in the art would have viewed the invention of the '988 patent as a patentable advancement over the prior art.

80. The claims of the '988 patent cover inventive spinal cord modulation for inhibiting pain with reduced side effects and associated systems and methods. BSC has infringed and continues to infringe one or more claims of the '988 patent, literally or under the doctrine of equivalents, including, without limitation, claim 1 in violation of 35 U.S.C. § 271(a) by manufacturing, using, selling and/or offering to sell in the United States certain SCS systems.

81. For example, claim 1 of the '988 patent recites:

- a) A method for programming a signal generator to deliver a therapy signal to a patient's spinal cord via at least one implantable signal delivery device, wherein the implantable signal delivery device is positioned to deliver the therapy signal to the patient's spinal cord at a vertebral level between T9 and T12, inclusively, the method comprising:
 - b) configuring the signal generator to generate a therapy signal, wherein the therapy signal is a plurality of bi-phasic pulses having a pulse width between 25 microseconds and 166 microseconds; and
 - c) programming the signal generator to deliver the therapy signal at a frequency and amplitude that at least partially reduces the patient's sensation of pain without generating paresthesia.

82. To the extent the preamble of claim 1 is considered a limitation, at least the BSC WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise a method for programming a signal generator to deliver a therapy signal to a patient's spinal cord via at least one implantable signal delivery device, wherein the implantable signal delivery device is positioned to deliver the therapy signal to the patient's spinal cord at a vertebral level between T9 and T12, inclusively. Additional information is set forth in Exhibit 8 at claim 1(a).

83. At least the BSC WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise configuring the signal generator to generate a therapy signal,

wherein the therapy signal is a plurality of bi-phasic pulses having a pulse width between 25 microseconds and 166 microseconds. Additional information is set forth in Exhibit 8 at claim 1(b).

84. At least the BSC WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise programming the signal generator to deliver the therapy signal at a frequency and amplitude that at least partially reduces the patient's sensation of pain without generating paresthesia. Additional information is set forth in Exhibit 8 at claim 1(c).

85. On information and belief, BSC knows of or has been willfully blind to the existence of the '988 patent. To protect its patented technology, on November 28, 2016, Nevro filed a patent infringement lawsuit against BSC in the Northern District of California alleging infringement of six patents directed to paresthesia-free therapy, including the '988 patent. BSC therefore has known of the '988 patent no later than November 28, 2016.

86. Nevro also asserted a claim of patent infringement against BSC in Delaware on December 9, 2019, based on another patent directed to paresthesia-free therapy (U.S. Patent No. 10,149,978). In those cases, Nevro provided BSC with detailed contentions explaining how BSC's SCS products infringe claims directed to paresthesia-free therapy. Accordingly, BSC has not only known or been willfully blind to the '988 patent, but BSC has also known that its SCS products infringe the '988 patent.

87. In past legal filings, BSC also alleged that "it is standard practice in the SCS industry to monitor competitors' patent portfolios" and that "[i]t is standard practice to conduct competitive intelligence when sued and to conduct a presuit investigation prior to initiating a lawsuit." Accordingly, on information and belief, BSC must itself monitor Nevro's patent portfolio, whereby BSC obtained actual and constructive knowledge of the Asserted Patents. On information and belief, BSC investigated Nevro's patent portfolio prior to copying Nevro's

paresthesia-free innovations, whereby BSC obtained actual and constructive knowledge of the '988 patent.

88. Furthermore, BSC has repeatedly referenced Nevro's website, www.nevro.com, in legal filings. On its website, Nevro identifies by patent number, issue date and title those patents, including the '988 patent, that may protect the Senza® system, either alone or in combination with its accessories, kits and procedures. Nevro's regular practice is to publish those relevant patents on its website. As a result, BSC has known or has been willfully blind to the existence of the '988 patent.

89. On information and belief, BSC has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use its SCS systems in a manner that infringes the '988 patent, literally or under the doctrine of equivalents. As is common in the SCS industry, BSC's clinical engineers and/or sales representatives are normally present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. BSC knows or has been willfully blind to the fact that such actions are inducing, and will induce, infringement. The foregoing actions by BSC constitute, and will constitute, induced infringement of one or more claims of the '988 patent in violation of 35 U.S.C. § 271(b).

90. On information and belief, BSC has contributed to infringement by others of one or more claims of the '988 patent by offering to sell or selling in the United States and/or importing into the United States its infringing SCS systems and/or components of its infringing SCS systems. As described above, these SCS systems and/or components are components of a patented machine, manufacture, combination or composition and constitute a material part of the

inventions claimed in the '988 patent. Also as described above, BSC knows or has been willfully blind to the fact that these infringing SCS systems and/or components are especially made or especially adapted for use in an infringement of the '988 patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use. As is common in the SCS industry, BSC has offered to sell, sold, and/or imported its infringing SCS systems and components to doctors, hospitals and other health care providers. These doctors, hospitals and other health care providers then make, use, sell, or offer to sell systems that utilize these infringing SCS systems and/or components. For example, BSC has represented that “[t]he WaveWriter Alpha 16 and WaveWriter Alpha Prime 16 SCS Systems support any combination of 8 Contact percutaneous, 16 Contact percutaneous, or 16 Contact Surgical Leads totaling up to 16 active Contacts.¹⁸ On information and belief, the infringing SCS systems are capable of incorporating other manufacturers' leads.¹⁹ The foregoing actions by BSC constitute, and will constitute, contributory infringement of one or more claims of the '988 patent in violation of 35 U.S.C. § 271(c).

91. BSC's infringement is without the consent or other authority of Nevro. BSC is not licensed under the '988 patent.

92. BSC's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285.

93. Nevro has been damaged by BSC's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, BSC's continued acts of

¹⁸ https://www.bostonscientific.com/content/dam/elabeling/nm/92395542-01_B_WaveWriter_Alpha_and_WaveWriter_Alpha_Prime_Implantable_Pulse_Generator_DFU_en-US_s.pdf, at 2.

¹⁹ *Id.* at 1-2 (listing compatible leads from other manufacturers).

infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring BSC from further infringement of the '988 patent.

FIFTH CAUSE OF ACTION
(Infringement of U.S. Patent No. 9,333,357)

94. Nevro incorporates paragraphs 1-93 as though fully set forth herein.
95. Nevro is the owner of all rights, title, and interest in and to the '357 patent.

The '357 patent issued on May 10, 2016, and is titled "Selective High Frequency Spinal Cord Modulation for Inhibiting Pain with Reduced Side Effects, and Associated Systems and Methods."

A copy of the '357 patent is attached as Exhibit 9.

96. The innovations of the '357 patent significantly improve existing SCS technology. The '357 patent explains, for example, how to "reduce[] pain by 42% when compared with standard SCS therapy," without paresthesia. 7:43-45. The '357 patent further explains how to inhibit pain "with reduced or eliminated side effects. Such side effects can include unwanted motor stimulation or blocking, and/or interference with sensory functions other than the targeted pain." 2:53-62. The '357 patent further explains how to "provide simplified spinal cord modulation systems and components, and simplified procedures for the practitioner and/or the patient." *Id.* The simplified procedures can include eliminating the conventional "trial and error process (or parts of this process) for identifying a suitable lead location and associated signal delivery parameters during the lead implant procedure," and also significantly simplifying "the process of selecting signal delivery parameters and administering the signals on a long-term basis." 5:58-60. The innovations of the '357 patent also enable patients to significantly improve their daily activities, "ranging from 30% for eating to 80%-90% for standing, walking and climbing stairs," compared to "only about 10%-20%" improvement using conventional SCS therapy. 8:30-49. This "greatly simplifies] the patient's life and reduce the effort required by the patient to

experience pain relief while engaging in a variety of activities.” 16:4-9. Patients also experienced less muscle spasms, cramps, and muscle pain, compared to standard SCS therapy. 9:21-26. The innovations of the ’357 patent further provide “amplitude “window” between the onset of effective therapy and the onset of pain or discomfort is relatively broad, and in particular, broader than it is for standard SCS treatment,” and also “allow the practitioner to provide modulation over a broader range of amplitudes” compared to conventional technology. 16:50-54, 17:24-27. Furthermore, using the ’357 patent’s innovations, “the practitioner need not implant the lead with the same level of precision as is typically required for standard SCS lead placement,” and may significantly reduce the “need for conducting a mapping procedure at the time the lead is implanted.” 17:50-54. The ’357 patent provides such benefits, while at the same time allowing easier design and manufacture, due to its superior technology. 23:47-48.

97. Accordingly, the claims of the ’357 patent provide a significant advancement over the prior art. For example, the prior art neither teaches nor suggests the claimed methods and apparatus for reducing or eliminating pain. These advancements were neither well-known, routine, nor conventional. On information and belief, a person of ordinary skill in the art would have viewed the invention of the ’357 patent as a patentable advancement over the prior art.

98. The claims of the ’357 patent cover inventive spinal cord modulation for inhibiting pain with reduced side effects and associated systems and methods. BSC has infringed and continues to infringe one or more claims of the ’357 patent, literally or under the doctrine of equivalents, including, without limitation, claim 1 in violation of 35 U.S.C. § 271(a) by manufacturing, using, selling and/or offering to sell in the United States certain SCS systems.

99. For example, claim 1 of the ’357 patent recites:

- a) A spinal cord modulation system for delivering an electrical therapy signal to a patient’s spinal cord, wherein the system is configured to deliver the

electrical therapy signal to the patient's spinal cord via one or more implantable signal delivery devices, the system comprising:

- b) a signal generator coupleable to the one or more signal delivery devices and having executable instructions to generate and deliver the electrical therapy signal to the patient's spinal cord from an epidural location via the one or more signal delivery devices,
- c) wherein the electrical therapy signal has a plurality of sequential bi-phasic pulses having a pulse width between 10 microseconds and 333 microseconds, and
- d) an amplitude between 0.5 mA and 10 mA, which at least partially reduces the patient's sensation of pain without generating paresthesia.

100. To the extent the preamble of claim 1 is considered a limitation, at least the BSC WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise a spinal cord modulation system for delivering an electrical therapy signal to a patient's spinal cord, wherein the system is configured to deliver the electrical therapy signal to the patient's spinal cord via one or more implantable signal delivery devices. Additional information is set forth in Exhibit 10 at claim 1(a).

101. At least the BSC WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise a signal generator coupleable to the one or more signal delivery devices and having executable instructions to generate and deliver the electrical therapy signal to the patient's spinal cord from an epidural location via the one or more signal delivery devices. Additional information is set forth in Exhibit 10 at claim 1(b).

102. At least the BSC WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise an electrical therapy signal that has a plurality of sequential bi-phasic pulses having a pulse width between 10 microseconds and 333 microseconds. Additional information is set forth in Exhibit 10 at claim 1(c).

103. At least the BSC WaveWriter Alpha, Alpha 16, Alpha Prime, and Alpha Prime 16 SCS systems comprise an electrical therapy signal with amplitude between 0.5 mA and 10 mA, which at least partially reduces the patient's sensation of pain without generating paresthesia. Additional information is set forth in Exhibit 10 at claim 1(d).

104. On information and belief, BSC knows of or has been willfully blind to the existence of the '357 patent. To protect its patented technology, on November 28, 2016, Nevro filed a patent infringement lawsuit against BSC in the Northern District of California alleging infringement of six patents directed to paresthesia-free therapy, including the '357 patent. BSC therefore has known of the '357 patent no later than November 28, 2016.

105. Nevro also asserted a claim of patent infringement against BSC in Delaware on December 9, 2019, based on another patent directed to paresthesia-free therapy (U.S. Patent No. 10,149,978). In those cases, Nevro provided BSC with detailed contentions explaining how BSC's SCS products infringe claims directed to paresthesia-free therapy. Accordingly, BSC has not only known or been willfully blind to the '357 patent, but BSC has also known that its SCS products infringe the '357 patent.

106. In past legal filings, BSC also alleged that "it is standard practice in the SCS industry to monitor competitors' patent portfolios," and that "[i]t is standard practice to conduct competitive intelligence when sued and to conduct a presuit investigation prior to initiating a lawsuit." Accordingly, on information and belief, BSC must itself monitor Nevro's patent portfolio, whereby BSC obtained actual and constructive knowledge of the Asserted Patents. On information and belief, BSC investigated Nevro's patent portfolio prior to copying Nevro's paresthesia-free innovations, whereby BSC obtained actual and constructive knowledge of the '357 patent.

107. Furthermore, BSC has repeatedly referenced Nevro's website, www.nevro.com, in legal filings. On its website, Nevro identifies by patent number, issue date and title those patents, including the '357 patent, that may protect the Senza® system, either alone or in combination with its accessories, kits and procedures. Nevro's regular practice is to publish those relevant patents on its website. As a result, BSC has known or has been willfully blind to the existence of the '357 patent.

108. On information and belief, BSC has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use its SCS systems in a manner that infringes the '357 patent, literally or under the doctrine of equivalents. As is common in the SCS industry, BSC's clinical engineers and/or sales representatives are normally present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. BSC knows or has been willfully blind to the fact that such actions are inducing, and will induce, infringement. The foregoing actions by BSC constitute, and will constitute, induced infringement of one or more claims of the '357 patent in violation of 35 U.S.C. § 271(b).

109. On information and belief, BSC has contributed to infringement by others of one or more claims of the '357 patent by offering to sell or selling in the United States and/or importing into the United States its infringing SCS systems and/or components of its infringing SCS systems. As described above, these SCS systems and/or components are components of a patented machine, manufacture, combination or composition and constitute a material part of the inventions claimed in the '357 patent. Also as described above, BSC knows or has been willfully blind to the fact that these infringing SCS systems and/or components are especially made or

especially adapted for use in an infringement of the '357 patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use. As is common in the SCS industry, BSC has offered to sell, sold, and/or imported its infringing SCS systems and components to doctors, hospitals and other health care providers. These doctors, hospitals and other health care providers then make, use, sell, or offer to sell systems that utilize these infringing SCS systems and/or components. For example, BSC has represented that “[t]he WaveWriter Alpha 16 and WaveWriter Alpha Prime 16 SCS Systems support any combination of 8 Contact percutaneous, 16 Contact percutaneous, or 16 Contact Surgical Leads totaling up to 16 active Contacts.²⁰ On information and belief, the infringing SCS systems are capable of incorporating other manufacturers' leads.²¹ The foregoing actions by BSC constitute, and will constitute, contributory infringement of one or more claims of the '988 patent in violation of 35 U.S.C. § 271(c).

110. BSC's infringement is without the consent or other authority of Nevro. BSC is not licensed under the '357 patent.

111. BSC's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285.

112. Nevro has been damaged by BSC's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, BSC's continued acts of infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring BSC from further infringement of the '357 patent.

²⁰ https://www.bostonscientific.com/content/dam/elabeling/nm/92395542-01_B_WaveWriter_Alpha_and_WaveWriter_Alpha_Prime_Implantable_Pulse_Generator_DFU_en-US_s.pdf, at 2.

²¹ *Id.* at 1-2 (listing compatible leads from other manufacturers).

PRAYER FOR RELIEF

WHEREFORE, Nevro respectfully requests judgment from this Court as follows:

A. The entry of judgment that BSC has directly infringed, literally or under the doctrine of equivalents, contributed to infringement of, and/or induced infringement of one or more claims of the Asserted Patents;

B. The entry of judgment that BSC has willfully infringed one or more claims of the Asserted Patents;

C. A judgment against BSC preliminarily and permanently enjoining BSC and its officers, employees, agents, attorneys, affiliates, successors, assigns, and others acting in privity or concert with them, and their parents, subsidiaries, divisions, successors and assigns, from further acts of infringement of the Asserted Patents

D. A judgment awarding Nevro damages resulting from BSC's infringement in an amount no less than a reasonable royalty or an amount equaling Nevro's lost profits due to BSC's infringement, and that such amount be multiplied based on BSC's willful infringement;

E. A judgment declaring that this is an exceptional case and awarding Nevro treble damages pursuant to 35 U.S.C. § 284 and attorneys' fees pursuant to 35 U.S.C. § 285;

F. A judgment against BSC that interests, costs, and expenses be awarded in favor of Nevro; and

G. Such other relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Nevro hereby demands trial by jury for all causes of action, claims, or issues that are triable as a matter of right to a jury.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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